510(k) Summary

OCT 0 4 2002

Contreet Hydrocolloid Dressing

Submitters name, address, phone and fax numbers

Coloplast Corporation
1955 West Oak Circle
Marietta, GA 30062-2249
USA
Phone: 770-281-8400
Fax: 770-345-8960

Contact person at Coloplast Corp

Elizabeth Boots
Vice President Quality Assurance
1940 Commerce Drive
PO Box 8300
North Mankato, MN 56002-8300
USA

Date 510(k) prepared

July 3, 2001

Name of the medical device

Trade name	Contreet Hydrocolloid Dressing
Common name	Topical wound dressing
Classification name	Dressing, wound and burn, occlusive (21CFR878.4020)

Legally marketed device to which substantial equivalence is claimed

Acticoat 7 Dressing (K001519)
ARGLAES-AB Antimicrobial Barrier Film and Island Dressings (K990810)
Comfeel Plus Ulcer Dressing (K941263)

Description of the device

Contreet Hydrocolloid Dressing is an antibacterial hydrocolloid dressing with silver providing an optimal moist wound healing environment.

Contreet Hydrocolloid Dressing has demonstrated in-vitro antibacterial activity in certain strains known to be detrimental to wound healing.

Contreet Hydrocolloid Dressing is a waterproof dressing with a semi-permiable film backing.

Intended use of the device

Contreet Hydrocolloid Dressing provides barrier protection against bacteria commonly encountered in wound ulcers.

Contreet Hydrocolloid Dressing is indicated for treatment of low to moderately exudating wounds.

Contreet Hydrocolloid Dressing is indicated for use for leg ulcers and pressure sores and may also be used for partial-thickness burns, donor sites, postoperative wounds and skin abrasions.

Contreet Hydrocolloid Dressing can be used on colonized wounds to support the wound healing and/or to reduce the odor from the wound.

Contreet Hydrocolloid Dressing can be used where the risk of infection is suspected or exists.

Contreet Hydrocolloid Dressing can be used on patients with wound infection at the discretion of the physician.

Contreet Hydrocolloid Dressing is suitable for use under compression bandaging on low to moderately exudating venous leg ulcers.

Summary of technological characteristics of subject device compared to predicate

Contreet Hydrocolloid Dressing compared to Comfeel Plus Ulcer Dressing: Comfeel is a hydrocolloid dressing and is the product that Contreet Hydrocolloid Dressing is based on. The only difference is that Contreet Hydrocolloid Dressing has silver incorporated into it. The indications for use that apply to Comfeel also apply to Contreet Hydrocolloid Dressing.

Contreet Hydrocolloid Dressing compared to Acticoat 7 Dressing and Arglaes-AB Antimicrobial Barrier Film and Island Dressings: All three dressings contain silver, which acts as an antimicrobial.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 04 2002

Ms. Betty Boots
Vice President, Quality Assurance
Coloplast Corporation
1940 Commerce Drive
N. Mankato, Minnesota 56003

Re: K013525
Trade/Device Name: Contreet Hydrocolloid Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: July 8, 2002
Received: July 8, 2002

Dear Ms. Boots:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of indications for use K 013525

Device Name: Contreet Hydrocolloid Dressing

Indications for Use:

The Contreet Hydrocolloid Dressing is indicated for use in the management of low to highly exudating leg ulcers, skin tears and pressure sores. The dressing can also be used for 2nd degree burns, 2nd degree partial thickness burns, donor sites, post operative wounds and skin abrasions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013525